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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,936	09/19/2003	Jack Chu	P1768 (MEDT/0024)	6819
28390	7590	11/21/2006	EXAMINER	
MEDTRONIC VASCULAR, INC.			KENNEDY, SHARON E	
IP LEGAL DEPARTMENT			ART UNIT	
3576 UNOCAL PLACE			PAPER NUMBER	
SANTA ROSA, CA 95403			1615	

DATE MAILED: 11/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/665,936

Applicant(s)

CHU ET AL.

Examiner

Sharon E. Kennedy

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-20 and 55-72 is/are pending in the application.
- 4a) Of the above claim(s) 20 and 56-72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-19 and 55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action or the MPEP.

Election/Restrictions

Applicant's election without traverse of Group I, claims 1, 3-19 and 55, in the reply filed on November 2, 2006, is acknowledged.

This application contains claims 20, 56-72 drawn to an invention nonelected without traverse in Paper No. 11/02/2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 101

Claims 1, 3-19 and 55 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The device is now claimed implanted in the aneurismal site. Essentially applicant is claiming a device in combination with the tissue, which is non-statutory subject matter. It is unlikely that applicant only wishes to sell and make the implant already inserted into a patient, or already implanted into excised aneurismal tissue.

Claim Rejections - 35 USC § 112

Claims 1, 3-19 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and indefinite because

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the reservoir is "implanted" into the patient/aneurysmal tissue. Clearly applicant wishes to make and sell the reservoir, and not protect the device only when implanted into a patient, or only when attached to an excised portion of vascular tissue comprising an aneurysm. Accordingly, the claims are unclear as to what is being claimed and does not give potential infringers the metes and bounds of the claims. Claim 1 is also vague and indefinite because it is unclear which component, the carrier or the reservoir, is delivering the therapeutic agent. Further regarding claim 5, the limitations of claim 5 are already recited in claim 1, accordingly, claim 5 is vague and indefinite. Applicant may argue that the claim is definite because both the carrier and the reservoir are releasing agent, however, that embodiment has not been disclosed.

Claims 1, 3-19 and 55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Especially regarding claim 5, this claim requires both the carrier and the reservoir to delivery agents to the aneurysmal tissue. The specification states in published paragraph [0008], "Thus, the reservoir may contain a carrier comprising a therapeutic agent, or the reservoir itself may comprise the therapeutic agent." The examiner cannot find a disclosure where both comprise the therapeutic agent at the same time. The remaining claims are rejected as well in view that claim 1 implies that the reservoir and not the carrier delivers the therapeutic agent.

Claim Rejections - 35 USC § 102

Claims 1, 3-6, 9, 11-19 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Urquhart, US 3,797,485.

Regarding claim 1, Urquhart discloses the reservoir 12 and carriers (column 12, lines 44+). The only difference between the claimed subject matter and the prior art is the use of the device to treat an aneurysm. However, the examiner points out that little patentable weight can be accorded to the environment of use of the device. See MPEP 2111.02, entitled "Effect of Preamble." It is well established that if a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See especially *In re Schreiber*, cited therein. A copy of the relevant portion is reproduced below for applicant's convenience.

309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962) (statement of intended use in an apparatus claim did not distinguish over the prior art apparatus). If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) (anticipation rejection affirmed based on Board's factual finding that the reference dispenser (a spout disclosed as useful for purposes such as dispensing oil from an oil can) would be capable of dispensing popcorn in the manner set forth in appellant's claim 1 (a dispensing top for dispensing popcorn in a specified manner)) and cases cited therein. See also MPEP § 2112 - § 2112.02.

In the alternative, although Urquhart does not specifically state a type of blood vessel treated, however, it would be obvious to one of ordinary skill in the art to use the Urquhart device to treat an aneurysm or any type of blood vessel in need of treatment. Special note is made of claims 17-20, again, as stated above, an article claim is not

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properly claimed in regard to how it is used, it is claimed by what it is. Applicant may say it is "adapted to be located" inside an aneurismal site, however, again, this intended use is accorded little patentable weight.

See MPEP 2114. The relevant portion is reproduced below.

APPARATUS CLAIMS MUST BE STRUCTU-RALLY DISTINGUISHABLE FROM THE PRIOR ART

>While features of an apparatus may be recited either structurally or functionally, claims< directed to >an< apparatus must be distinguished from the prior art in terms of structure rather than function. >*In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997) (The absence of a disclosure in a prior art reference relating to function did not defeat the Board's finding of anticipation of claimed apparatus because the limitations at issue were found to be inherent in the prior art reference); see also *In re Swinehart*, 439 F.2d 210, 212-13, 169 USPQ 226, 228-29 (CCPA 1971);< *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). "[A]pparatus claims cover what a device *is*, not what a device *does*." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original).

Regarding claim 3, although Urquhart does not explicitly state "time release", applicant should be aware that the carriers perform that function. Note the suspending agents recited in the end of column 12. Regarding claim 9, the biostable polymers are disclosed in column 7, lines 22+. Regarding claim 11, the natural polymers are disclosed in reference to the carrier. Regarding claim 15, note the list in column 12, lines 15+.

Claim Rejections - 35 USC § 103

Claims 7, 8, 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Urquhart '485. These claims recite specific polymers. In the lack of a showing of

criticality, it would be obvious to one of ordinary skill in the art to use the more "modern" polymers recited in applicant's claims.

Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Urquhart '485 in view of Leonhardt et al., US '917.

Regarding claim 55, if the Urquhart device were used in conjunction with an aneurysm, it would be obvious to one of ordinary skill in the art to apply a stent to the vessel as shown by Leonhardt et al., US 5,713,917, so that the vessel could be stabilized, dependent upon the patient need.

Response to Arguments

Applicant's arguments filed August 31, 2006 have been fully considered but they are not persuasive. Applicant has detailed information regarding the phrase "incorporation by reference." Applicant should be aware that this has legal status when examining claims for essential material. See 37 CFR 1.57. Used otherwise, when discussing a prior art rejection, it is merely a phrase without legal status. It is regretted that applicant was confused by the phrase. The examiner should have said "referred to" instead of "incorporation by reference."

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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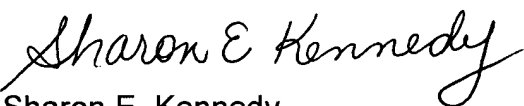
§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon E. Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571/272-8373.


Sharon E. Kennedy
Primary Examiner
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